### § 5.40 Issuance of Federal Register documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use.

The Director and Deputy Director, Center for Veterinary Medicine (CVM) are authorized to issue FEDERAL REGISTER documents pertaining to the determination of safe levels, notice of need for development of an analytical method, notice of availability of a developed analytical method, and prohibition of certain extralabel drug use related to implementation of the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103–396). This authority may be further redelegated by the Director and Deputy Director, CVM.

[62 FR 43471, Aug. 14, 1997]

### § 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For new animal drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) The following officials are authorized, under section 802(f) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, CBER.

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For veterinary drugs subject to their jurisdiction:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act, to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Director, CBER.

(2) The Director and Deputy Director, Office of Compliance, CBER.

[52 FR 7269, Mar. 10, 1987, as amended at 54 FR 8317, Feb. 28, 1989; 62 FR 2555, Jan. 17, 1997]

### § 5.45 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the FFDCA.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the FFDCA.

(4) Supervise such compliance actions.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug